IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

DU PLESSIS

Serial No. 10/557,192

Filed: July 31, 2006

Atty. Ref.: 511-70

Group: 1616; Conf. No. 1113

Examiner: Arnold, Ernst V.

For: PREPARATION OF AN OSTEOINDUCTIVE AGENT

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November 30, 2009

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RULE 132 DECLARATION OF TJAART ANDRIES DU PLESSIS

I, Tjaart Andries Du Plessis, declares and states as follows:

1. I am the named inventor in the above-identified application. I hold a PhD in Radiation Chemistry and acts as an expert advisor to the International Atomic Energy Agency, and have 45 years' experience in the field of radiation processing.

2. I have reviewed the Office Action issued by the U.S. Patent Office in my application on July 28, 2009.

3. I have also reviewed U.S. Patent No. 6,610,810 issued to Phillips *et al.* and cited by the Examiner in his rejection of my application the July 28, 2009 Office Action. I am the Tjaart Andries Du Plessis named as one of the co-inventors in the Phillips patent.

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4. My invention is directed to, among other things, a cost-effective, sterile and user friendly kit for medical professionals in the orthopedic environment. The kit is used to prepare and dispense an osteoinductive agent, which includes a plurality of biocompatible biopolymers that are first mixed together before being subjected to a source of ionising radiation.

5. While it is known that radiation is useful for sterilizing products, there are advantages to first mixing the biocompatible biopolymers used in my invention and then radiating the product. These advantages include (i) enhanced cross-linking of the biopolymers, (ii) a decrease in production time and costs, eliminating the steps of first radiating the products separately, and thereafter, mixing them and radiating the product again before packaging, and (iii) reducing the chances for contamination.

6. Radiation is a cold process and is, therefore, especially applicable to plastics disposables, as it will not distort the plastic. Therefore, to ensure sterility of the final product of my invention, the entire kit (the modified naturally occurring biocompatible biopolymer and the primary, secondary and tertiary containers) is sealed in plastic and radiated again to ensure that the product is sterile and ready for use by medical professionals in the orthopedic sterile environment.

7. Since May of 2003, 5250 units of my kit have been sold to the National

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Tissue Bank of the University of Pretoria and to Southern Medical (Pty) Ltd., collectively. In addition, the National Tissue Bank has exported 450 of these units to various foreign countries. More recently, Celtis Medzintechnologie GmbH, an Austrian company, has taken a technology license that grants them the exclusive right to manufacture and promote units of my kit in Europe.

8. Although I am a common inventor between my application and the Phillips patent, my application and the Phillips patent are not commonly assigned/owned to the same entity, and they are not subject to a joint research agreement.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patents issuing thereon.

27th November 2009 _____
Date

_____
Tjaart Andries Du Plessis

United States Patent and Trademark Office

Assignments on the Web > Patent Query

Patent Assignment Abstract of Title

NOTE:Results display only for issued patents and published applications. For pending or abandoned applications please consult USPTO staff.

Total Assignments: 1

Patent #: NONE **Issue Dt:** **Application #:** 10557192 **Filing Dt:** 07/31/2006

Publication #: 20060275336 **Pub Dt:** 12/07/2006

Inventor: Tjaart Andries Du Plessis

Title: Preparation of an osteoinductive agent

Assignment: 1

Reel/Frame: 018173/0071 **Recorded:** 07/31/2006 **Pages:** 2

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignor: DU PLESSIS, TJAART ANDRIES **Exec Dt:** 11/29/2005

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Patent Assignment Abstract of Title

NOTE:Results display only for issued patents and published applications. For pending or abandoned applications please consult USPTO staff.

Total Assignments: 2

Patent #: 6610810 **Issue Dt:** 08/26/2003 **Application #:** 09805385 **Filing Dt:** 03/13/2001

Publication #: 20030027883 **Pub Dt:** 02/06/2003

Inventors: Glyn Owen Phillips, Tiaart Andries Du Plessis, Saphwan Al-Assaf et al

Title: BIOPOLYMERS OBTAINED BY SOLID STATE IRRADIATION IN AN UNSATURATED GASEOUS ATMOSPHERE

Assignment: 1

Reel/Frame: 014718/0251 **Recorded:** 11/24/2003 **Pages:** 13

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

Assignors: PHILLIPS, GLYN O. **Exec Dt:** 08/19/2003

DU PLESSIS, TJAART A. **Exec Dt:** 08/13/2003

AL-ASSAF, SAPHWAN **Exec Dt:** 08/18/2003

WILLIAMS, PETER A. **Exec Dt:** 08/19/2003

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Assignment: 2

Reel/Frame: 016153/0584 **Recorded:** 01/21/2005 **Pages:** 3

Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).

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